EXAMPLE - GENERAL INFORMATION

1. Originator

a.	Originator Name	Inert Manufacturers, Inc.
b.	Technical Contact	Dr. Edgar Bee 226 Hive St. Honeywell, CA 00000 Phone: (000) 111-0000 Fax: (000) 111-0001 ebee@hive.com
c.	Submittal Date	06/23/01

2. Chemical ID

a.	Name	Chemical C
b.	Synonyms	Chem-X, diphenyl X
c.	CAS #	1111-00-1
d.	Physical/Chemical Properties	Physical Form (neat) Molecular Weight = 220 Log octanol-water partition coefficient (Log Kow) = 3.4 Vapor Pressure (25°C) = 5.0E-4 mmHg Water Solubility (25°C) = 120 mg/L Melting Point = -15°C Boiling point = 120°C HLC (25°C) = 2.3E-6 atm m^3/mol Density (25°C) = 1.6 g/mL
		Photolysis: half life = 23 days Hydrolysis: half life = 10 days Biodegradation: half life = 15 months (water) Transport/distribution = Soil - 80% Water - 5% Sediment - 10% Air - 5%

3. Volume and End Use

		Units	Total US		Assessed	
		☐ pounds ☐ kilograms	Volume/year	percent	Volume/year	percent
a.	Volume	Manufactured	1,300,000	100	1,000,000	75
		Imported	0	0	0	0
		Total	1,300,000	100	1,000,000	75
b.	Uses	Indoor Insecticide	1,300,000	100	1,300,000	100
		Other	0	0	0	0
		Export	0	0	0	0

EXAMPLE - GENERAL INFORMATION

3. Volume and End Use (continued)

c. Life cycle: Chemical C is a chemical in commerce which is manufactured at our facility and sold to processing facility X to formulate the pesticide product Pest-X. Chemical C is an inert ingredient in Pest-X. Pest-X is used at numerous households as an insecticide. Empty product containers of Pest-X are landfilled.

4. Executive Summary

EXAMPLE - GENERAL INFORMATION

a. Characterization of Completeness - This assessment was designed to examine exposure to Chemical C that is manufactured at our facility and is processed as the inert (other) ingredient in the pesticide product, Pest-X, that is processed at Pesticide Formulators, Inc. The volume assessed in this submittal represents the only use of the chemical, as sold by our company, and accounts for 100 percent of the volume produced by our facility, and 75 percent of the national volume of the chemical produced. During the manufacturing of Chemical C, there are potential exposures to workers from indoor air releases and from dermal contact with Chemical C. Worker exposures that have been assessed include potential exposure to female employees, and the potential exposure that can be passed on to their children. Modeling has been conducted to assess the exposure that can occur to infants who consume the breast milk of women who work in the manufacturing facility for 8 hours per day. Occupational exposure has recently been addressed with the use of personal protective equipment and engineering controls. There are also potential exposures to the public from air and water releases. No monitoring data have been collected for surface water releases. No direct monitoring data were obtained linking releases from the manufacturing or use of Chemical C to exposure from incidental inhalation among local residents. However, the results from EPA's Industrial Source Complex-Long Term (ISCLT) model were used to estimate potential exposures to the general population from fugitive air emissions from our manufacturing facility. Data are currently being collected that will allow for a more accurate estimate of fugitive releases. These data will be used to evaluate the ability of the model to estimate downwind concentrations, which, in turn, may allow the company to better estimate exposures to the general population. During the processing of Chemical C, there are potential exposures to workers from indoor air releases of Chemical C, which are assessed here, based on data from Pesticide Formulators, Inc. Also, there are potential exposures to the public from air and water releases. Exposures from air and water releases from the processing facility have not yet been assessed because release data are currently being collected that would allow us to estimate exposures to the general population. Potential residential exposures could occur from indoor crack and crevice treatments (i.e., inhalation and dermal during application, and inhalation, dermal, and, non-dietary ingestion postapplication). These potential exposures have been evaluated via a combination of monitoring and modeling assessments. There are no expected exposures to Chemical C among commercial applications because Pest-X is not labeled for use by professional commercial applicators. Exposure from drinking water was assessed based on monitoring data from groundwater. These data are not associated with a specific release, but may be related to non-point sources of agricultural chemicals. Aggregate exposure among children was also assessed to account for non-dietary, dermal, and inhalation exposures.

b. Synthesis of Key Assessment Results - All of the exposure estimates for this assessment were based on conservative or median- to high-end values and are therefore considered high-end screening estimates only. Further characterization of exposure estimates may be found in the discussion of the individual pathways and aggregate exposure scenarios. These estimates may be useful for comparison to toxicity reference doses in the Tier 1 risk assessment. Exposure of infants of nursing mothers who work at the manufacturing facility has been estimated to be as high as 0.025 mg/kg/day. Potential exposure of the adult general public from fugitive air emissions from our manufacturing facility have been estimated as 1.36×10^{-04} µg/kg/day, based on the ISCLT model. Inhalation exposure among processors was very low (i.e., no Chemical C was detected in personal monitoring devices). Dermal exposures were not monitored because processing occurs via a closed system. Indoor dermal exposures among adult handlers ranged from 0.009 to 0.017 mg/kg/day (APDR); 2.8×10^{-4} to 5.6×10^{-4} mg/kg/day (ADD). Inhalation exposures were very low (i.e., 7.1×10^{-7} to 1.4×10^{-6} mg/kg/day [APDR]; 2.4×10^{-8} to 4.7×10^{-8} mg/kg/day [ADD]). Postapplication dermal exposure among children was estimated to be 0.4 mg/kg/day (APDR and ADD). Non-dietary ingestion exposure was 0.13 mg/kg/day (APDR) and 0.063 mg/kg/day (ADD), and inhalation exposures were below detection limits within 1 hour after application. Based on a national groundwater study conducted by DoD, acute exposure to Chemical C from ingestion of groundwater among 3-year old children was estimated to average 0.017 µg/kg/day. Chronic exposure was estimated to be 0.0067 µg/kg/day. Aggregate acute exposure (i.e., from multiple sources) to Chemical C was estimated to be 0.53 mg/kg/day for 3-year old children. Aggregate chronic exposure was 0.46 mg/kg/day.

EXAMPLE - GENERAL INFORMATION

4. Executive Summary (Continued)

c. Discussion of Key Uncertainties, Limitations, and Data Gaps - A single breast milk sample was collected from each of 4 women who worked at our manufacturing facility in Idaho. It is uncertain whether the data collected from this monitoring study are representative of other operations or the nation as a whole. The ISCLT model used to estimate exposure to the general public only accounts for the contribution of one facility. It does not consider Chemical C inputs from other sources. The values estimated are likely not representative of the additive effects of other facilities in nearby locations. The model also does not account for the presence of other chemicals in the atmosphere, and their possible additive effects on the toxicity of Chemical C. Monitoring data for processors were based on limited data (15 individuals) from a single facility in which a closed system is used. These data would not be representative of facilities with open processing. Indoor exposure among residents are based on data collected from 5 residences and may not be entirely representative of all housing types and conditions in the U.S. Indoor dermal and non-dietary ingestion estimates for children are based on modeling assumptions in EPA's Residential SOPs and are likely to be conservative. Drinking water exposure estimates are based on groundwater monitoring data for various sites across the U.S. that may be biased towards compounds found on Federal facilities.

d. Summary of Data Collection Effort - In preparing this exposure summary, we identified exposure studies for manufacturers, processors, and residential users. Exposure to infants was estimated based on a single study of four nursing women from our facility. General population exposure from air emissions was based on a single modeling run using input data for our facility. Inhalation exposure to processors have also been assessed based on a single study. Residential exposures have been assessed for adult handlers and children who are exposed from Chemical C remaining after application. Dietary exposures have also been estimated for children. We conducted a literature search and identified a national survey of groundwater. The results of this study that are pertinent to Chemical C are presented here. These data, along with the other exposure estimates for children, are used to provide an aggregate assessment for children.

EXAMPLE - GENERAL INFORMATION

4. **Executive Summary** (Continued)

e. Contents

Summary of Releases and Exposure	Summary of Monitoring Evaluations	Summary of Modeling Evaluations
1. Manufacturing	**a.** Exposure of infants of working mothers	**b.** General population exposure from fugitive air emissions
2. Processing	**c.** Worker inhalation exposure	None
3. Use 1 - Indoor Residential Crack and Crevice Treatment	**d.** Adult handler exposures (dermal and inhalation)	**f.** Dermal and hand-to-mouth post-application exposure
	e. Postapplication inhalation exposure	
4. None (no associated use or release information available)	**g.** Ingestion of groundwater	None
5. None (various uses)	None	**h.** Aggregate children's exposure

EXAMPLE - GENERAL INFORMATION

4. Executive Summary (Continued)

f. Table of Exposure Results

Scenario	Acute Exposures APDR (mg/kg/day)	Chronic Exposures ADD (mg/kg/day)	Population
breast feeding infants of working mothers	0.003 - 0.025	0.003 - 0.025	infants
air release to environment during manufacturing	1.36×10^{-7} (maximum dose)		local population around manufacturing facility
inhalation of indoor air at processing facility	$< 7.0 \times 10^{-6}$	$< 5.0 \times 10^{-6}$	workers in processing facility
inhalation of indoor residues during application	7.1×10^{-7} to 1.4×10^{-6}	2.4×10^{-8} to 4.7×10^{-8}	adult applicators
dermal contact with indoor residues during application	0.009 to 0.017	2.8×10^{-4} to 5.6×10^{-4}	adult applicators
inhalation of indoor residues post-application	$<3.0 \times 10^{-6}$	$<3.0 \times 10^{-6}$	child
dermal contact with indoor residues post-application	0.4	0.4	child
non-dietary ingestion of indoor residues post-application	0.13	0.063	child
ingestion of groundwater	1.7×10^{-5}	6.7×10^{-6}	child
aggregate exposure	0.53	0.46	child

5. References

Kirk Othmer, Encyclopedia of Chemical Technology, Third Edition, 1983.
U.S. EPA. 1997. Residential SOPs.

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 1 Description: Manufacturing

1. Activity and Associated Volume

Activity type	Function/Application/Setting	Volume
☐ Manufacturing	Chemical C is manufactured for use as an inert ingredient in pesticide formulations. The chemical is produced by a reaction of Chemical V with Chemical Z. The reaction forms a crude product, which is purified to yield a useable grade of the chemical.	10,000 lbs/yr
☐ Processing/Formulation		
☐ Use		

2. Physical Form and Concentration

As Received:

Form:	☐ Dry Powder	☐ Pellets or Large Crystals	☐ Water or Solvent Wet Solid	☐ Gas or Vapor	☐ Liquid	☐ Other
Concentration:	N/A					

As it leaves the site:

Form:	☐ Dry Powder	☐ Pellets or Large Crystals	☐ Water or Solvent Wet Solid	☐ Gas or Vapor	☐ Liquid	☐ Other
Concentration:					100%	

Description: Chemical C is manufactured as an inert ingredient for use in pesticide formulations.

3. Site Information

a. Site Type

☐ Residential

☐ Commercial/Industrial

☐ Industrial

b. Number of Sites	Total US Sites (indicate if estimate)	Sites addressed in this assessment
	9	1

c. Site Locations: The manufacturing facility is located at 1 Main Street, Our Town, ID.

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 1 Description: Manufacturing

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 1 Description: Manufacturing

5. Release Information (Continued)

Specify units: ☐ lbs Or kgs	Estimated Total Annual Releases	# days/year release occurs
A. On-site Air Release		
Fugitive	900	365
Stack	100	365

Basis for Estimate (attach additional calculations as desired): Based on published emission factors for similar process, the manufacturing of Chemical Cy which is analogous in structure to Chemical C, and is also manufactured using identical unit operations.

B. Water Releases from Site		
Water Releases	NA	
Receiving water name:	NPDES #:	
Basis for Estimate (attach additional calculations as desired):		
C. On-Site Land Releases		
Landfill	NA	
Land Treatment/ Land Amendment	NA	
Surface Impoundment	NA	
Underground Injection	NA	
Other (specify)	NA	
Basis for Estimate (attach additional calculations as desired):		
D. Off-site Transfers		
D1. Transfer to Publicly Owned Treatment Works (POTWs)	NA	

POTW Name:

Street Address:

City: County:

State: Zip Code:

NPDES number:

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 1 Description: Manufacturing

Basis for Estimate (attach additional calculations as desired):

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 1 Description: Manufacturing

5. Release Information (Continued)

Specify units: ☐ lbs Or kgs		Estimated Total Annual Releases	# days/year release occurs
D2.	Transfers To Other Off-Site Locations		
	Incineration	NA	
	Wastewater Treatment (Excluding POTW)	NA	
	Underground Injection	NA	
	Hazardous Waste (RCRA Subtitle C) landfill	100	1
	Other landfill	NA	
	Recycle or Recovery	NA	
	Unknown or Other	NA	

Basis for Estimate (attach additional calculations as desired): pulled from previous waste manifest

6. Engineering Controls, Personal Protective Equipment, and Regulatory Requirements

a. Engineering Controls - During the manufacturing process, the greatest potential for releases of the Chemical are to the air. These emissions are collected from process vents and the building exhaust fans. Activated carbon filters are used to treat these emissions prior to being vented to the environment. Areas of the facility where the product is handled (e.g., storage tank to truck transfer stations) are well ventilated to protect the workers from prolonged exposure to chemical vapors. Production tanks have berms to contain at least 10 percent of the tank volume.

b. Personal Protective Equipment - Employees that are exposed to Chemical C at the facility during the performance of their duties are allowed to wear any type of clothing that fully covers the skin (i.e., long pants and long sleeve shirts). To prevent prolonged skin surface exposure, the facility also provides PVC gloves. Employees that are exposed to the solid waste sludge generated by the facility during the performance of their duties wear similar clothes, in addition to respirators provided by the company. Skin should be washed promptly when contaminated.

c. Regulatory Requirements - The facility reports annual mass releases under the TRI reporting, is a full quantity generator under the RCRA regulations, and is covered by the MACT air emission regulations. Facility operators comply with OSHA health and safety protocols as discussed above.

Occupational Standards:		Federal Environmental Standards:		
TLV:	100 ppm	TRI:	Yes	SWDA contaminant: No
PEL:	10 ppm	HAP:	Yes	CERCLA reportable quantity: 1 lb
		CWA Priority Pollutant:	No	
STEL:	50 ppm	RCRA U&P Waste:	UUUU	
		Others:		

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 1 Description: Manufacturing

7. Summary of Exposure Results

Potential exposure could occur among workers or the general population residing in the vicinity of the manufacturing facility. Inhalation is the most likely route of exposure. Concentrations of Chemical C in the wastewater from the facility have not been modeled or monitored. Ambient air concentrations downwind of the manufacturing facility have not been monitored for Chemical C. However, EPA's ISCLT model has been used to estimate ambient air concentrations. Data are currently being collected that will allow for a more accurate estimate of fugitive releases. These data will be used by the model to estimate downwind concentrations, which, in turn, may provide better exposure estimates to the general population. Potential exposures to infants has been documented related to the consumption of breast milk of women who work in the manufacturing facility for 8 hours per day.

Occupational, General Population, and Consumer Exposure Summary:

(1) Activity	(2) Physical Form		(3) Number of Persons Exposed	(4) Maximum Duration	
	(a) Form	(b) Conc.		Hours/day	Days/year
a. infants of working mothers	breast milk	0.11 mg/L	4	NA	365
b. air release (environment)	gas	4.74×10^{-4} µg/m^3	4,000 (estimate of local population)	24	365

8. References

AP-42, Compilation of Air Pollutant Emission Factors, 1995
Joe Chemist, Emission data, 1998

9. Contents

Summary of Monitoring Evaluations Associated with this Release	Summary of Modeling Evaluations Associated with this Release
a. Exposure of infants of working mothers	b. General Population Exposure from fugitive air emissions

EXAMPLE - SUMMARY OF MONITORING EVALUATIONS

Activity #: 1 Description: Manufacturing
Evaluation: a Description: Exposure of infants of working mothers

1. Technical Contact

a. Name	Dr. LJP University of Important Study Emission District Smalltown, ID 00000
b. Phone Number	(000) 000-0000; fax: (000) 000-0001
c. E-mail Address	fillintheblanks@university.org

2. Date of Monitoring Study

01/01/01

3. Monitoring Study Objective

The objective of the study was to estimate the concentration of Chemical C in the breast milk of nursing mothers that were exposed to Chemical C. The strategy was to examine different scenarios that would cover most of the occupational exposures associated with Chemical C.

4. Exposure Assessment Objective

The objective of the assessment was to generate conservative estimates of acute and chronic exposures to infants associated with the consumption of breast milk that was contaminated with Chemical C.

5. Sampling Methods

Single breast milk samples were collected from each of 4 women who worked at our facility that manufactures Chemical C. Samples of approximately 50 mL were collected. Samples were collected, stored, and shipped to the laboratory at 4°C. Only minimal physiological data were collected for the 4 subjects. Sample chain of custody forms were used to track samples.

6. Analytical Chemistry Methods

SW 846, Method XXXX was used to analyze the samples. (U.S., EPA, 1986). Analyses were performed by ABC Laboratories in Main Town, PA.

EXAMPLE - SUMMARY OF MONITORING EVALUATIONS

Activity #: 1 Description: Manufacturing
Evaluation: a Description: Exposure of infants of working mothers

7. QA/QC Procedures

The data collected during the monitoring study were screened for use in the exposure assessments. Quality assurance objectives were outlined in a Quality Assurance Plan that was prepared as part of the study and before sampling began (University of Important Study, 2001). The Plan outlined the QA/QC procedures that were followed by the laboratory. To check the validity of the results from the lab, a single blind duplicate was submitted. Negative (i.e., blank) control samples were also analyzed. All of the quality assurance objectives that were set were met. All quality control procedures have been employed and documented.

8. Results

a. Monitoring Results - Breast milk concentrations ranged from 0.03 to 0.26 mg/L Chemical C with a mean of 0.11 mg/L over 4 samples.

b. Exposure Estimates - Chemical C intake for infants was estimated to range from 0.003 to 0.025 mg/kg/day. Exposure to infants was estimated based on the assumptions of a breast milk intake of 0.7 L/day and an infant body weight of 7.2 kg. (U.S. EPA, 1989). The Acute Potential Dose Rates (APDRs) were calculated as follows:

APDRs = (Breast Milk Concentration) x (Consumption Rate) / (Body Wt)
0.003 mg/kg/day = (0.03 mg/L) x (0.7 L/day) / (7.2 kg)
0.025 mg/kg/day = (0.26 mg/L) x (0.7 L/day) / (7.2 kg)

Average Daily Doses (ADDs) were the same as APDRs because the same exposure occurs every day over the duration of breast feeding (i.e., 1 year).

9. Uncertainty

Factors such as body weight, race, and proximity of the subjects' residences to the facility were not addressed. These factors could have contributed to or detracted from the effects of Chemical C on the subject. Other potential sources of Chemical C exposure were not evaluated.

10. References

ATSDR Chemical Profile for Chemical C, 1997.
U.S. EPA, 1989. Exposure Factors Handbook.
U.S. EPA. 1986. Test Methods for Evaluating Solid Waste; Physical Chemical Methods SW 846.
University of Important Study. 2001. QA/QC Plan.

EXAMPLE - SUMMARY OF MODELING EVALUATIONS

Activity #: 1 Description: Manufacturing
Evaluation: b Description: General population exposure from fugitive air emissions

1. Technical Contact

a. Name	Dr. J. Doe The Framis Factory 321 Release Way Anytown, ID 00000
b. Phone Number	(000) 000-0000; fax: (000) 000-0001
c. E-mail Address	lindajane@theframisfactory.com

2. Modeling Study Objective

The objective of the modeling study was to estimate the maximum chronic dose to the general population associated with the air emissions that are generated at our manufacturing facility.

3. Model Name, Version Number, Run Date

Industrial Source Complex-Long Term (ISCLT) Model - Incorporated into:
PC-based, Graphical Exposure Modeling System (PC-GEMS), V2.05, 1995

4. Evaluation/Peer Review Status of Model

The ISCLT model has been validated with monitoring data that is directly relevant for the scenario of interest (Modeler, 1996). The model has been through a formal peer review process (Reviewer, 1998).

5. Availability of Model

PCGEMS is included in the Exposure Models Library and Integrated Model Evaluation System, a CD-ROM issued by EPA's Office of Research and Development. The CD-ROM is a collection of EPA tools for exposure and risk assessment. For information about the availability of PCGEMS, please contact:
Lynn Delpire
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460
202-260-3928

6. Key Model Inputs

The following inputs were used to model the stack emissions from the facility:
Stack Height = 61.2 m
Exit Velocity = 2 m/s
Diameter = 5 m
Source Emission = 4.536 kg/year (1.44×10^{-4} g/s)
Default model inputs were used for all other parameters

EXAMPLE - SUMMARY OF MODELING EVALUATIONS

Activity #: 1 Description: Manufacturing
Evaluation: b Description: General population exposure from fugitive air emissions

7. Model Algorithm/Assumptions

The model algorithm and assumptions are discussed on EPA's web site, and therefore, are not repeated here.

8. Description of Exposure Scenario

The scenario modeled is for a single point-source emission from a facility. We used the exit vent from our facility building exhaust fan as the point source. The ISCLT model estimates the maximum concentration of Chemical C in ambient air in the vicinity of the facility, and the maximum dose to the exposed population, based on our inputs from Section 6 of this form.

9. Results

The maximum concentration calculated by the ISCLT model was 4.74×10^{-04} µg/m^3. The maximum dose calculated by the ISCLT model was 1.36×10^{-04} µg/kg/day. As mentioned above, the model algorithm and assumptions are discussed on EPA's web site, and therefore, are not repeated here. Similarly, it is not necessary to repeat the equations used by the model.

10. Uncertainty

The model accounts for the contribution of only one facility. It does not consider Chemical C inputs from other sources. The values estimated are likely not representative of the additive effects of other facilities in nearby locations. The model also does not account for the presence of other chemicals in the atmosphere, and their possible additive effects on the toxicity of Chemical C.

11. References

AP-42, Compilation of Air Pollutant Emission Factors, 1995
ATSDR Chemical Profile for Chemical C, 1997.
Modeler, A. 1996. Validation of ISCLT Model.
Reviewer, D. 1998. Peer Review of ISCLT Model.
U.S. EPA, 1997. Exposure Factors Handbook.
Users manual for the Industrial Source Complex-Long Term (ISCLT) Model, 1995

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 2 Description: Processing

1. Activity and Associated Volume

Activity type	Function/Application/Setting	Volume
☐ Manufacturing		
☐ Processing/Formulation	Chemical C is purchased from Inert Manufacturers, Inc. and delivered on trucks to Pesticide Formulators, Inc. where it is unloaded via pump to a mixing vessel where it is processed into the formulated product (Pest-X) at a concentration of 50% pesticide and 50% liquid inert ingredients (Chemical C).	10,000 lb/yr
☐ Use		

2. Physical Form and Concentration

As Received:

Form:	☐ Dry Powder	☐ Pellets or Large Crystals	☐ Water or Solvent Wet Solid	☐ Gas or Vapor	☐ Liquid	☐ Other
Concentration:					100%	

As it leaves the site:

Form:	☐ Dry Powder	☐ Pellets or Large Crystals	☐ Water or Solvent Wet Solid	☐ Gas or Vapor	☐ Liquid	☐ Other
Concentration:					50%	

Description: Chemical C is formulated into a 50% emulsifiable concentrate to be diluted 1:10 in water by the user.

3. Site Information

a. Site Type

☐ Residential

☐ Commercial/Institutional

☐ Industrial

b. Number of Sites	Total US Sites (indicate if estimate)	Sites addressed in this assessment
	10	1

c. Site Locations: The processing facility is located at 0 Fairfax Street, New City, NJ.

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 2 Description: Processing

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 2 Description: Processing

5. Release Information (Continued)

Specify units: ☐ lbs Or kgs	Estimated Total Annual Releases	# days/year release occurs
A. On-site Air Release		
Fugitive	5,000	
Stack	NA	

Basis for Estimate (attach additional calculations as desired): Estimated based on published information on the formulation of Pesticide-Ya which is analogous in structure to Pest-X, and is also produced using a similar process. Data for our plant are currently being collected and will be available at a later date.

B. Water Releases from Site		
Water Releases	5,000	
Receiving water name:	NPDES #:	

Basis for Estimate (attach additional calculations as desired): Estimated based on published information on similar processes. Data for our plant are currently being collected and will be available at a later date.

C. On-Site Land Releases		
Landfill	NA	
Land Treatment/ Land Amendment	NA	
Surface Impoundment	NA	
Underground Injection	NA	
Other (specify)	NA	

Basis for Estimate (attach additional calculations as desired):

D. Off-site Transfers

D1.	Transfer to Publicly Owned Treatment Works (POTWs)	NA	

POTW Name:
Street Address:
City: County:
State: Zip Code:
NPDES number:

Basis for Estimate (attach additional calculations as desired):

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 2 Description: Processing

5. Release Information (Continued)

Specify units: ☐ lbs Or kgs		Estimated Total Annual Releases	# days/year release occurs
D2.	Transfers To Other Off-Site Locations		
	Incineration	NA	
	Wastewater Treatment (Excluding POTW)	NA	
	Underground Injection	NA	
	Hazardous Waste (RCRA Subtitle C) landfill	NA	
	Other landfill	NA	
	Recycle or Recovery	<10	
	Unknown or Other	NA	

Basis for Estimate (attach additional calculations as desired): Estimate based on the number of empty containers returned to the manufacturer, assuming that the amount of Chemical C in the empty container represents <0.1% of the amount in the original container.

6. Engineering Controls, Personal Protective Equipment, and Regulatory Requirements

a. Engineering Controls - A closed mixing and closed mechanized packaging system are used during processing.
b. Personal Protective Equipment - PPE is not required in this plant because of the use of a closed system.
c. Regulatory Requirements - Workers are covered by OSHA requirements.

Occupational Standards:
TLV: 100 ppm
PEL: 10 ppm
STEL: 50 ppm

Federal Environmental Standards:
TRI: Yes
HAP: Yes
CWA Priority Pollutant: No
RCRA U&P Waste: UUUU
Others:

SWDA contaminant: No
CERCLA reportable quantity: 1 lb

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 2 Description: Processing

7. Summary of Exposure Results

Potential inhalation exposures were found to be very low (i.e., below the limit of detection of 0.05 µg/m^3) based on personal monitoring of workers in the processing plant. Based on the limit of detection, an assumed inhalation rate of 1.2 m^3/hr, and an exposure duration of 8 hrs/day, exposure was estimated to be <0.007 µg/kg/day. Dermal exposure was not monitored.

Occupational, General Population, and Consumer Exposure Summary:

(1) Activity	(2) Physical Form		(3) Number of Persons Exposed	(4) Maximum Duration	
	(a) Form	(b) Conc.		Hours/day	Days/year
a. Inhalation of Indoor Air	gas	<0.05 µg/m^3	15 (estimated number of workers in processing facility)	8	250

8. References

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9. Contents

Summary of Monitoring Evaluations Associated with this Release	Summary of Modeling Evaluations Associated with this Release
Monitoring data for air and water releases from the processing facility are currently being collected. Thus, general population exposures are not assessed.	
c. Worker inhalation exposure	-----

EXAMPLE - SUMMARY OF MONITORING EVALUATIONS

Activity #: 2 Description: Processing
Evaluation: c Description: Worker Inhalation Exposure

1. Technical Contact

a. Name	JMB 46 Nowhere St. Someplace, NJ 00000
b. Phone Number	000-000-0000; Fax: 000-000-0001
c. E-mail Address	JMB@pestx.com

2. Date of Monitoring Study

2/19/00

3. Monitoring Study Objective

This study collected personal inhalation monitoring samples and analyzed them for Chemical C to generate data to be used to evaluate potential exposures among workers in a Pest-X formulating plant.

4. Exposure Assessment Objective

The objective of the exposure assessment was to generate conservative estimates of acute and chronic exposures to processors of Chemical C who use a closed system to formulate Pest-X. A screening-level assessment was conducted using the detection limit for the air samples because no measurable Chemical C was observed in the samples collected.

5. Sampling Methods

Dual personal monitors were attached at the breathing zone of workers conducting typical activities in the processing plant where Pest-X is formulated with Chemical C as an inert ingredient. A closed mixing and packaging system is used. A total of 15 workers involved in various activities were monitored for a period of 8 hours. Sampling pumps ran at a volume of 2 L/minute for the duration of the study. At the end of the 8-hour monitoring period, sampling cassettes were capped, labeled, and stored on dry ice during shipment to the analytical laboratory. Data on the physiological characteristics (i.e., height, weight, age, etc.) and work activities of the 15 workers was also collected.

6. Analytical Chemistry Methods

SW 846, Method XXXX was used to analyze the samples. (U.S. EPA, 1986). Analyses were performed by XYZ Laboratories in Nowhere, NJ.

7. QA/QC Procedures

All of the data collected during the monitoring study were screened for use in the exposure assessments. Quality assurance objectives were outlined in a Quality Assurance Plan prepared before sampling began. The Plan outlined the QA/QC procedures that were followed by the laboratory. Replicate inhalation sampling devices were used for each worker to check the reproducibility of the analyses. Negative (blank) control samples and field spikes were also analyzed. All of the quality assurance objectives that were set were met. All quality control procedures have been employed and documented.

EXAMPLE - SUMMARY OF MONITORING EVALUATIONS

Activity #: 2 Description: Processing
Evaluation: c Description: Worker Inhalation Exposure

8. Results

a. Monitoring Results - Chemical C was not found above the detection limit of 0.05 µg/m^3 were observed.
b. Exposure Estimates - Based on the limit of detection, exposure to Chemical C was estimated to be <0.007 µg/kg/day.

APDR = Concentration x Inhalation Rate x Exposure Time/Body Weight

<0.007 µg/kg/day = <0.05 µg/m^3 x 1.2 m^3/hr x 8 hr/d / 70 kg

The inhalation rate of 1.2 m^3/hr represents the rate for workers at a moderate activity level provided in the Exposure Factors Handbook (U.S. EPA, 1997). An assumed workday of 8 hrs was used, and a mean body weight of 70 kg was used (U.S. EPA, 1997). The ADD was estimated to be <0.005 µg/kg/day based on 250 days out of 365 days per year of exposure.

9. Uncertainty

The study only addresses potential exposure at a single facility that uses closed mixing and packaging. The results can not be applied to exposures at facilities using other types (e.g., open) of systems.

10. References

U.S. EPA, 1997. Exposure Factors Handbook
U.S. EPA, 1986. Test Methods for Evaluating Solid Waste - SW 846

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 3 Description: Use 1 - Indoor Residential Crack and Crevice Treatment

1. Activity and Associated Volume

Activity type	Function/Application/Setting	Volume
☐ Manufacturing		
☐ Processing/Formulation		
☐ Use	Indoor Residential Crack and Crevice Treatment	5,000 lb/yr

2. Physical Form and Concentration

As Received:						
Form:	☐ Dry Powder	☐ Pellets or Large Crystals	☐ Water or Solvent Wet Solid	☐ Gas or Vapor	☐ Liquid	☐ Other
Concentration:					50%	
As it leaves the site:						
Form:	☐ Dry Powder	☐ Pellets or Large Crystals	☐ Water or Solvent Wet Solid	☐ Gas or Vapor	☐ Liquid	☐ Other
Concentration:				1%	50%	

Description: Pest-X is formulated as an emulsifiable concentrate containing 50% inert ingredient, Chemical C. The user dilutes the formulation 1:10 in water before use in the home.

3. Site Information

a. Site Type

☐ Residential

☐ Commercial/Institutional

☐ Industrial

b. Number of Sites	Total U.S. Sites (indicate if estimate)	Sites addressed in this assessment
	numerous consumer use locations	5

c. Site Locations: Pest-X, containing 50% inert Chemical C, is used as a crack and crevice treatment in residences to control a variety of insects at various consumer use sites.

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 3 Description: Use 1 - Indoor Residential Crack and Crevice Treatment

4. Process Description

Pest-X may be purchased over the counter by consumers. Prior to use, it is diluted 1:10 in water. It is applied via specially-designed hand sprayer that is packaged and sold with the product. Pest-X should be applied along baseboards and in cracks in the basement floor.

5. Release Information

During spraying, Chemical C is released to the air in the form of an aerosol and also may be released as a vapor it dries. Residues are released to treated surfaces in the intended treatment areas. Although the spray system that is sold with the Pest-X product has been specifically designed to limit overspray, some releases may also occur in unintended treatment areas.

Specify units: ☐ lbs Or kgs	Estimated Total Annual Releases	# days/year release occurs
A. On-site Air Release		
Fugitive	1,000	unknown
Stack	NA	
Basis for Estimate (attach additional calculations as desired): Estimate based on published emission factors for a related chemical and professional judgement.		
B. Water Releases from Site		
Water Releases	NA	
Receiving water name:	NPDES #:	
Basis for Estimate (attach additional calculations as desired):		
C. On-Site Land Releases		
Landfill	NA	
Land Treatment/ Land Amendment	NA	
Surface Impoundment	NA	
Underground Injection	NA	
Other (specify)	989,000	unknown
Basis for Estimate (attach additional calculations as desired): Indoor treatments. Based on the assumption that the majority of product is applied in the home (i.e., 1,000,000 lb/year minus 10,000 lbs/yr released to air as fugitive release minus 1,000 lbs/yr remaining in containers that are landfilled).		

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 3 Description: Use 1 - Indoor Residential Crack and Crevice Treatment

5. Release Information (Continued)

Specify units: ☐ lbs Or kgs		Estimated Total Annual Releases	# days/year release occurs
D. Off-site Transfers			
D1.	Transfer to Publicly Owned Treatment Works (POTWs)	NA	
	POTW Name:		
	Street Address:		
	City: County:		
	State: Zip Code:		
	NPDES number:		
	Basis for Estimate (attach additional calculations as desired):		
D2.	Transfers To Other Off-Site Locations		
	Incineration	NA	
	Wastewater Treatment (Excluding POTW)	NA	
	Underground Injection	NA	
	Hazardous Waste (RCRA Subtitle C) landfill	NA	
	Other landfill	1,000	
	Recycle or Recovery	NA	
	Unknown or Other	NA	
	Basis for Estimate (attach additional calculations as desired): Estimate based on the number of containers assumed to be discarded by residents. Assumes that the same number of containers sold are also discarded and that the residual amount of Chemical C in the empty containers represents <0.1% of the chemical in the original container.		

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 3 Description: Use 1 - Indoor Residential Crack and Crevice Treatment

6. Engineering Controls, Personal Protective Equipment, and Regulatory Requirements

a. Engineering Controls - The specially designed sprayer system sold with the pesticide product has been engineered to direct Pest-X to the intended areas and limited unnecessary releases to the home.
b. Personal Protective Equipment - Homeowners are not expected to use any form of PPE during use of this product.
c. Regulatory Requirements - This product is labeled for residential use under FIFRA. The label provides the recommended uses, application rates (e.g., Pest-X, containing 50% Chemical C, should be diluted 1:10 in water; 0.005 lb ai/100 ft^2 to treat a 100 ft^2 room), timing of application (e.g., once per month), and recommended application equipment. It also provides information on safety hazards and storage. Although not covered by the Federal Regulations, some local municipalities may govern the disposal of empty containers as household hazardous waste.

Occupational Standards:	Federal Environmental Standards:	
TLV: NA	TRI:	SWDA contaminant:
PEL: NA	HAP:	CERCLA reportable quantity:
STEL: NA	CWA Priority Pollutant:	
	RCRA U&P Waste:	
	Others:	

7. Summary of Exposure Results

Exposure to Chemical C can occur as a result of dermal contact and inhalation during handling of the Pest-X product (i.e., mixing, loading, and applying). These exposures are assumed to occur among adult handlers. Based on a monitoring study conducted in 5 homes, potential dermal exposures (ADDs) were estimated to range from $2.8x10^{-4}$ to $5.6x10^{-4}$ mg/kg/day. Inhalation exposures (ADDs) ranged from $2.4x10^{-8}$ to $4.7x10^{-8}$ mg/kg/day. Based on another monitoring study in the same 5 homes, postapplication inhalation exposures would be expected to be low (i.e., no detectable Chemical C was observed in stationary monitors set at the breathing zone of children in homes treated with Pest-X). Based on modeling, postapplication dermal exposure (APDR) among children was estimated to be 0.4 mg/kg/day and non-dietary (hand-to-mouth) exposure was 0.13 mg/kg/day. The ADD for dermal exposure is the same as the APDR because the exposures are assumed to occur every day, but the non-dietary APDR is lower (0.063 mg/kg/day) because a lower frequency on hand-to-mouth activity is assumed over the long term.

EXAMPLE - SUMMARY OF RELEASES AND EXPOSURE

Activity #: 3 Description: Use 1 - Indoor Residential Crack and Crevice Treatment

7. Summary of Exposure Results (continued)

Occupational, General Population, and Consumer Exposure Summary:

(1) Activity	(2) Physical Form		(3) Number of Persons Exposed	(4) Maximum Duration	
	(a) Form	(b) Conc.		Hours/day	Days/year
a. Inhalation of indoor residues during application	gas	0.1 - 0.2 µg/m^3	~10,000	0.5	12
b. Dermal contact with indoor residues during application	liquid	0.075 - 0.015 mg/cm^2	~10,000	NA	12
c. Inhalation of indoor residues post-application	gas	<0.006 µg/m^3	~20,000	24	365
d. Dermal contact with indoor residues postapplication	dry residue	–	~20,000	4	365
e. Non-dietary ingestion of indoor residues post-application	dry residue	–	~20,000	4	365

8. References

U.S. EPA (1998) Series 875, Group B, Guidelines for Postapplication Exposure Monitoring

9. Contents

Summary of Monitoring Evaluations Associated with this Release	Summary of Modeling Evaluations Associated with this Release
d. Adult handler exposures e. Postapplication inhalation exposure	f. Dermal and hand-to-mouth postapplication exposure

EXAMPLE - SUMMARY OF MONITORING EVALUATIONS

Activity #: 3 **Description:** Use 1 - Indoor Residential Crack and Crevice Treatment
Evaluation: d **Description:** Adult Handler Exposures

1. Technical Contact

a. Name	James Smith 222 Forest St. Woods, NB 00000
b. Phone Number	444-444-4444; Fax: 444-555-4455
c. E-mail Address	smithjames@pestx.com

2. Date of Monitoring Study

4/7/00

3. Monitoring Study Objective

The purpose of this study was to collect data that could be used to evaluate potential dermal and inhalation exposure to Chemical C during indoor residential application of Pest-X

4. Exposure Assessment Objective

The objective was to estimate high-end acute and chronic dermal and inhalation exposure among consumers who apply Pest-X in their homes.

5. Sampling Methods

A total of 5 adult volunteers were asked to use Pest-X according to the label directions. Each individual was asked to treat a single room, measuring approximately 100 ft^2, in different houses in California at the recommended application rate. The individuals wore 100% cotton full body dermal dosimeters, cotton gloves, and dual personal inhalation monitors, clipped to their collars, in the breathing zone. Personal monitors were set to run at approximately 2 L/minute for the duration of the application process (i.e., 30 minutes). After application was complete, the personal monitoring cassettes were removed, capped, and placed on dry ice for shipment to the lab. Dermal dosimeters were removed, cut into pieces representing various body parts (i.e., arms, legs, torso), and placed in plastic bags for shipment to the laboratory. Gloves were also removed and sent to the lab. Concentrations of Chemical C on the face and neck were sampled using moistened gauze wipes measuring 100 cm^2. The wipes were placed in plastic bags and shipped on dry ice to the laboratory.

6. Analytical Chemistry Methods

The analytical method used was developed and validated by Pest-Labs Inc. in Orange, California. The method is titled PS 280 R.

7. QA/QC Procedures

All of the data collected during the monitoring study were screened for use in the exposure assessments. Quality assurance objectives were outlined in a Quality Assurance Plan prepared before sampling began. The Plan outlined the QA/QC procedures that were followed by the laboratory. Replicate inhalation sampling devices were used for each worker to check the reproducibility of the analyses. Negative (blank) control samples and field spikes were also analyzed. All of the quality assurance objectives that were set were met. All quality control procedures have been employed and documented.

EXAMPLE - SUMMARY OF MONITORING EVALUATIONS

Activity #: 3 **Description:** Use 1 - Indoor Residential Crack and Crevice Treatment
Evaluation: d **Description:** Adult Handler Exposures

8. Results

a. Monitoring Results - Chemical C was observed only on the glove dosimeters indicating that potential dermal exposure occurs only to the hands. The concentration of Chemical C on the gloves ranged from 0.0075 to 0.015 mg/cm^2. Chemical C in the personal inhalation monitors ranged from 0.1 to 0.2 µg/m^3.

b. Exposure Estimates - Dermal acute potential dose rates (APDRs) were estimated to range from 0.009 to 0.017 mg/kg/day using a surface area of the hands of 800 cm^2, an absorption rate of 10%, and a body weight of 70 kg. This is based on values in the Exposure Factors Handbook (U.S. EPA, 1997) and the concentrations of Chemical C observed on the dermal dosimeters.

APDR = Concentration x Skin Surface Area x Absorption Fraction / Body Weight
0.009 to 0.017 mg/kg/day = 0.0075 to 0.015 mg/cm^2 x 800 cm^2/day x 0.1 / 70 kg

The average daily doses (ADDs) were estimated to range from 0.00028 to 0.00056 mg/kg/day. This is based on the assumption that an individual's long-term exposure is equivalent to the APDR times the exposure frequency 12 days/year/365 days/year.

Inhalation APDRs were estimated to range from 0.0007 to 0.0014 µg/kg/day, using assumptions from the Exposure Factors Handbook (U.S. EPA, 1997) (i.e., 1 m^3/hr inhalation rate for light activity level and a body weight of 70 kg (U.S. EPA, 1997) and an exposure time of ½ hour).

Daily Dose = Concentration x Inhalation Rate x Exposure Time / Body Weight
0.0007 to 0.0014 µg/kg/day = 0.1 to 0.2 µg/m^3 x 1 m^3/hr x ½ hr/day / 70 kg

9. Uncertainty

This study was limited to 5 homes and may not be representative of all housing types or geographic regions. There is also uncertainty associated with the absorption factor used. This factor was based on a study using pigskin to simulate absorption through human skin.

10. References

Pest-Labs Inc. (1997) Validation of Method PS 280 R for Analysis of Chemical C.
Pesticide Formulators (1998) Draft Study on Handler Exposure to Pest-X.
Pesticide Formulators (2000) Absorption of Chemical C Through Pig Skin. Draft Report.
U.S. EPA (1997) Exposure Factors Handbook.
U.S. EPA (2000) Series 875, Group B. Guidelines for Postapplication Exposure Monitoring.

EXAMPLE - SUMMARY OF MONITORING EVALUATIONS

Activity #: 3 **Description:** Use 1 - Indoor Residential Crack and Crevice Treatment
Evaluation: e **Description:** Postapplication Inhalation Exposure

1. Technical Contact

a. Name	James Smith 222 Forest St. Woods, NB 00000
b. Phone Number	444-444-4444; Fax: 444-555-4455
c. E-mail Address	smithjames@pestx.com

2. Date of Monitoring Study

4/7/00

3. Monitoring Study Objective

The purpose of this study was to monitor indoor residential air concentrations after application of Pest-X. The data may be used to evaluate the dissipation kinetics of Chemical C in the indoor environment and to evaluate potential inhalation exposures.

4. Exposure Assessment Objective

The objective of the study was to generate conservative estimates of acute and chronic inhalation exposures to Chemical C among children residing in homes where Pest-X is used for crack and crevice treatment. Although the data may also be used to address adult exposures, the focus of the study was on children because they were assumed to be the most sensitive population. Exposure on a body weight basis was expected to be higher among children than adults. The study used the detection limit for Chemical C in air to calculate inhalation exposures because no measurable concentrations of Chemical C were observed in air.

5. Sampling Methods

Stationary monitors were placed in 5 locations in a 100 ft^2 room, within the breathing zone of a child (a distance of 1 meter from the floor). The monitors ran at a rate of 10 L/minute for a 4-hour period with sampling cassettes being changed each hour. At the end of each 1-hour sampling period, sampling cassettes were capped, labeled, and stored on dry ice until shipment to the analytical laboratory. A total of 5 homes in California were used in the study.

6. Analytical Chemistry Methods

The analytical method used was developed and validated by Pest-Labs Inc. in Orange, California. The method is titled PS 280 R.

7. QA/QC Procedures

All of the data collected during the monitoring study were screened for use in the exposure assessments. Quality assurance objectives were outlined in a Quality Assurance Plan prepared before sampling began. The Plan outlined the QA/QC procedures that were followed by the laboratory. Replicate inhalation sampling devices were used to check the reproducibility of the analyses. Negative (blank) control samples and field spikes were also analyzed. All of the quality assurance objectives that were set were met. All quality control procedures have been employed and documented.

EXAMPLE - SUMMARY OF MONITORING EVALUATIONS

Activity #: 3 **Description:** Use 1 - Indoor Residential Crack and Crevice Treatment
Evaluation: e **Description:** Postapplication Inhalation Exposure

8. Results

a. Monitoring Results - No Chemical C above the detection limit of 0.006 µg/m^3 was observed.
b. Exposure Estimates - Based on the limit of detection for Chemical C and the recommended inhalation rate for children as cited in EPA's Exposure Factors Handbook (U.S. EPA, 1997), inhalation exposure (acute potential dose rate) to Chemical C among children was estimated to be <0.003 µg/kg/day.

APDR = Concentration x Inhalation rate / Body Weight
<0.003 µg/kg/day = <0.006 µg/m^3 x 8.3 m^3/day / 15 kg

An inhalation rate of 8.3 m^3/day represents a mean daily rate for 3-5 year old children (U.S. EPA, 1997), and a body weight of 15 kg represents the weight for a 3-year old child (U.S. EPA, 1997). The average daily dose (ADD) is the same as the APDR because the same exposure occurs every day.

9. Uncertainty

This study was limited to 5 homes in California. These homes may not be entirely representative of all U.S. homes.

10. References

U.S. EPA (1997) Exposure Factors Handbook.
U.S. EPA (1998) Series 875, Group B. Guidelines for Postapplication Exposure Monitoring.

EXAMPLE - SUMMARY OF MODELING EVALUATIONS

Activity #: 3 **Description:** Use 1 - Indoor Residential Crack and Crevice Treatment
Evaluation: f **Description:** Dermal and Hand-to-Mouth Postapplication Exposure

1. Technical Contact

a. Name	James Smith 222 Forest St. Woods, NB 00000
b. Phone Number	444-444-4444; Fax: 444-555-4455
c. E-mail Address	smithjames@pestx.com

2. Modeling Study Objective

The purpose of this modeling exercise was to provide a conservative estimate of acute and chronic dermal and hand-to-mouth exposure based on the application rate and default exposure assumptions for hard surfaces. Exposures were assessed on the day of application (i.e., assumes no dissipation) to provide upper percentile estimates.

3. Model Name, Version Number, Run Date

SOPs for Residential Exposure Assessment, Sections 8.2.2 and 8.4. U.S. EPA, 2001. Run 4/7/01. This is not a computerized model. It is a document prepared by EPA's Office of Pesticide Programs that provides algorithms and assumptions for various pesticide exposure scenarios.

4. Validation/Peer Review Status of Model

The SOPs document has been developed and internally reviewed by various EPA offices and the Science Advisory Panel.

5. Availability of Model

Document available from U.S. EPA.

6. Key Model Inputs

The necessary inputs to this model are the application rate and default assumptions described below.

7. Model Algorithm/Assumptions

Absorbed Dermal Acute Potential Dose Rate (APDR) (mg/kg/day) = indoor surface residue (mg/cm^2) x transfer coefficient (cm^2/hr) x absorption fraction x exposure time (hr/day) / body weight (kg).
Indoor Surface Residue = application rate (lbs/ft^2) x fraction of residue retained on surface.
Hand-to-Mouth Acute Potential Dose Rate (APDR) (mg/kg/day) = indoor surface residue (mg/cm^2) x skin surface area (cm^2/event) x frequency of hand-to-mouth events (events/hr) x saliva extraction fraction x exposure time (hrs/day) / body weight (kg).
The assumptions were as follows: 10% of the application rate is available for dislodging, the transfer coefficient is 6,000 cm^2/hr for toddlers, and the exposure time is 4 hours/day. Exposure is assessed on the day of application (i.e., no dissipation). Surface area is assumed to be 20 cm^2/event (hands) for toddlers; frequency is 20 events/hour; saliva extraction factor is 50%. Body weight is assumed to be 15 kg, and absorption is assumed to be 10% for Chemical C. The Dermal Average Daily Dose (ADD) is calculated as the APDR times the exposure frequency of 365 days per year and the exposure duration of one year divided by the averaging time of one year times 365 days/yr. The Hand-to-Mouth ADD uses an APDR with a hand-to-mouth frequency of 9.5 events/hr and is calculated as the APDR times an exposure frequency of 365 d/yr for one year divided by an averaging time of one year times 365 days/yr.

EXAMPLE - SUMMARY OF MODELING EVALUATIONS

Activity #: 3 **Description:** Use 1 - Indoor Residential Crack and Crevice Treatment
Evaluation: f **Description:** Dermal and Hand-to-Mouth Postapplication Exposure

8. Description of Exposure Scenario

The scenarios assessed here assume Chemical C is transferred to the skin of a toddler (3-year old child) who comes into contact with areas treated with Pest-X, such as floors and counter tops during play activities. Exposure occurs from dermal uptake and/or hand-to-mouth contact.

9. Results

Based on modeling, postapplication dermal exposure (i.e., APDR and ADD) among 3-year old children was estimated to be 0.4 mg/kg/day, and non-dietary (hand-to-mouth) exposure was 0.13 mg/kg/day (APDR) and 0.063 mg/kg/day (ADD).

10. Uncertainty

Uncertainties occur from assumptions regarding dissipation and transfer of Chemical C. The transfer coefficient is based on data for adults (scaled to children) (Cal EPA, 1996). Also, uncertainties exist related to skin surface area, hand-to-mouth frequency, and absorption factor. The absorption fraction is based on a single study using pigskin to evaluate dermal uptake of Chemical C. According to U.S. EPA (2001), the exposure estimates generated by this method are assumed to represent high-end exposures. Because a combination of central tendency and high-end, conservative inputs were used, the estimates are believed to be upper percentile values.

11. References

U.S. EPA, 2001. Standard Operating Procedures for Residential Exposure Assessment.
CAL EPA, 1996. Memorandum regarding transfer coefficients.
Pesticide Formulators, 2000. Absorption of Chemical C Through Pig Skin. Draft Report.

EXAMPLE - SUMMARY OF MONITORING EVALUATIONS

Activity #: 4 Description: No Associated Use
Evaluation: g Description: Ingestion of Groundwater

1. Technical Contact

a. Name	W.E. Norton 466 Water Way Riverton, GA 00001
b. Phone Number	555-000-0000; Fax: 555-000-0001
c. E-mail Address	wen@gw.com

2. Date of Monitoring Study

March 1995

3. Monitoring Study Objective

The study was conducted by DoD to examine levels of a variety of chemicals in the nation's groundwater.

4. Exposure Assessment Objective

The data from the DoD Groundwater Study were used to generate conservative estimates of acute and chronic exposure to Chemical C from ingestion of groundwater among children. Although dermal exposure and inhalation from household use of groundwater were also considered to be potential routes of exposure to Chemical C, exposure via these routes were not presented in the assessment. Also, the exposure assessment focused on children (ages 3-5 years). Exposure estimates for other age groups were not provided.

5. Sampling Methods

A total of 563 groundwater samples were collected from monitoring wells across the country. In general, existing monitoring wells from previous studies on Federal (i.e., DoD) facilities were used. Samples (500 mL) were drawn from the wells, placed in amber bottles, and shipped to the laboratory on dry ice for analysis.

6. Analytical Chemistry Methods

DoD Method PX-346 for the analysis of chemicals in groundwater was used to analyze the samples for Chemical C and other compounds. This method uses HPLC to quantify Chemical C.

7. QA/QC Procedures

All of the data collected during the monitoring study were screened for use in the exposure assessments. Quality assurance objectives were outlined in a Quality Assurance Plan that was prepared as part of the study before sampling began. The Plan outlined the objective and scope of the study and the QA/QC procedures that were followed by the laboratory. Replicate inhalation sampling devices were used for each worker to check the reproducibility of the analyses. Negative (blank) control samples and field spikes were also analyzed. All of the quality assurance objectives that were set were met. All quality control procedures have been employed and documented.

EXAMPLE - SUMMARY OF MONITORING EVALUATIONS

Activity #: 4 Description: No Associated Use
Evaluation: g Description: Ingestion of Groundwater

8. Results

a. Monitoring Results - Chemical C was detected in 486 of the 563 groundwater samples analyzed. The detection limit was 0.1 µg/L. The mean concentration was 0.25 µg/L.
b. Exposure Estimates - Using the mean concentration of 0.25 µg/L, an ingestion rate of 1 L/day and a body weight of 15 kg, the acute potential dose rate (APDR) to a 3-year old child would be 0.017 µg/kg/day

APDR = Concentration x Intake Rate / Body Weight

0.017 µg/kg/day = 0.25 µg/L x 1 L/day / 15 kg

The intake rate and body weight used are based on data in EPA's Exposure Factors Handbook for a 3-year old child (U.S. EPA, 1997). The intake rate is a high-end value. The average daily dose (ADD) is somewhat lower (6.7×10^{-3} µg/kg/day) because an ingestion rate of 0.4 L/day was used instead of 1 L/day. the ADD exposure is assumed to occur every day.

9. Uncertainty

The monitoring study concentrated sampling efforts near Federal facilities. It is uncertain whether these locations are representative of the nation as a whole. Also, because other potential routes of exposure (i.e., dermal and inhalation) were not assessed, the exposure estimates provided by this study may be underestimated.

10. References

DoD (1995) National Groundwater Study.
U.S. EPA (1997) Exposure Factors Handbook.

EXAMPLE - SUMMARY OF MODELING EVALUATIONS

Activity #: 5 Description: Various Uses
Evaluation: h Description: Aggregate Children's Exposure

1. Technical Contact

a. Name	SP Multiple 2053 Double Knit Dr. Twin Cities, MN 00000
b. Phone Number	552-000-0000; Fax: 552-000-0001
c. E-mail Address	twins@mn.com

2. Modeling Study Objective

The purpose of this assessment was to generate conservative estimates of acute and chronic total exposure to Chemical C among 3-year old children from multiple pathways.

3. Model Name, Version Number, Run Date

This is not a model per se, but is an algorithm set up in a spreadsheet to sum the estimated doses to a 3-year old child from various exposure pathways.

4. Validation/Peer Review Status of Model

Not applicable.

5. Availability of Model

Not applicable.

6. Key Model Inputs

The inputs used for assessing aggregate exposure are the exposure estimates for 3-year old children presented in the various monitoring and modeling forms provided in this submission.

7. Model Algorithm/Assumptions

Because the toxicity endpoints for Chemical C are the same for dermal, oral, and inhalation exposure, estimated doses from the following exposure pathways were added to estimate the aggregate short-term dose: ingestion of groundwater; indoor postapplication inhalation, dermal, and non-dietary ingestion (i.e., hand-to-mouth) dose. Inhalation of Chemical C in fugitive emissions was not included in the aggregate exposure calculations for children because such exposures were negligible; compared to those based on other exposure pathways. Also, 3-year old children were assumed to spend their entire day in an indoor environment (i.e., inhaling indoor air) to be conservative. The assumptions are as follows: (1) both acute and long-term chronic inhalation exposure among 3-year old residential children is 0.003 µg/kg/day, based on indoor air concentrations at the detection limit; (2) both acute and long-term chronic dermal exposure among residential children is 0.4 mg/kg/day, based on a modeling study intended to calculate upper-percentile estimates; (3) acute non-dietary ingestion exposure among residential children is 0.13 mg/kg/day and long-term chronic exposures are 0.063 mg/kg/day, based on a modeling study intended to calculate upper-percentile estimates; and (4) acute drinking water ingestion exposure is 0.017 µg/kg/day and long-term chronic exposure is 0.0067 µg/kg/day, based on the mean groundwater concentration of Chemical C.

EXAMPLE - SUMMARY OF MODELING EVALUATIONS

Activity #: 5 Description: Various Uses
Evaluation: h Description: Aggregate Children's Exposure

8. Description of Exposure Scenario

The exposure scenario presented here is for a 3-year old child who may be exposed to Chemical C via multiple pathways in a single day. This assumes that the child lives in a home treated with Chemical C and that on the day the child is exposed to postapplication concentrations of Chemical C via inhalation, dermal contact with hard surfaces, and hand-to-mouth contact, the child also consumes groundwater and tomatoes contaminated with Chemical C at the tolerance level. The purpose was to estimate an upper range estimate of exposure using primarily high-end exposure estimates from the various pathways for the purpose of a screening level risk assessment for Chemical C.

9. Results

The aggregate dose from all pathways was estimated as follows, with dermal contact accounting for the majority of the exposure.

Aggregate Dose = Inhalation Dose + Dermal Dose + Non-dietary Dose + Dietary (food) Dose + Dietary (water) Dose
Acute Aggregate Dose = 0.53 mg/kg/day = 3E-6 mg/kg/day + 0.4 mg/kg/day + 0.13 mg/kg/day + 1.7E-5 m/kg/day
Chronic Aggregate Dose = 0.46 mg/kg/day = 3E-6 mg/kg/day + 0.4 mg/kg/day + 0.063 mg/kg/day + 6.7E-6 mg/kg/day

10. Uncertainty

The uncertainties associated with this assessment stem from the use of high-end exposure estimates for all pathways. It is not clear that exposure in a single individual from all pathways would occur simultaneously at the high-end of the distribution. Also, it is uncertain that the toxicity of Chemical C is the same for all routes of exposure.

11. References

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